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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,799	12/20/2001	Beuford Arlie Bogue	24720	4794

7590 07/02/2003

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/02/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,799

Applicant(s)

BOGUE, BEUFORD ARLIE

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: .

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DETAILED ACTION

Receipt of IDS dated 4-15-02, declaration, extension of time, fee, dated 7-1-02 and preliminary amendment a dated 12-20-01 is acknowledged.

Claims 1-28 are pending.

Claim Rejections - 35 USC § 103

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,197,349 to Westesen et al ('349).

'349 teach drug delivery systems comprising particles made of super cooled melt of a poorly water-soluble substance and a stabilizing agent, where the mean particle size is between 30 and 500 nm (abstract, col.7, lines 25-54). The particles of '349 exist primarily in amorphous phase (col.1). '349 teach that solubilization of otherwise insoluble drugs cab be achieved by reducing particle size or improving wettability of particles by hydrophilization or by reducing crystallinity of the substance (col. 2, lines 13-60). In particular, "349 teach that the addition of surfactants as wetting agents increase the wettability of particles, which can be further increased if the drug is not in crystalline form but in amorphous form, because the latter exhibits high solubility and fast dissolution that their crystal forms (col. 5, lines 30-56). For the process of preparing the microparticles, '349 teaches preparing a dispersion of water-insoluble drug with a stabilizer (such as surfactants), which is then emulsified above the melting point of the substance or mixture of substances (col. 10, lines 1-26) and then subject to vortexing (which reads on shear force) resulting in fine particle preparation. Further, '349 teach that ionic and nonionic surfactants stabilize the particles formed in the above process and suggest several surfactants (col.12) for stabilization. '349 teach choosing a proper emulsifier prevents the de-crystallization

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of the substances. '349 teach several drugs or therapeutics (col. 13) and teach the final particle size of below 150 nm (col. 14). '349 does not state whether the drug and surfactant are chemically bonded. '349 also fails to state if a matrix is formed between drug and substance and also if the substance is free flowable as in claim 18. However, '349 teaches the same steps of mixing the surfactants with the drugs that are poorly soluble and emulsified above melting point of the mixture, which is accomplished only by heating and accordingly, absent showing evidence to the contrary, a matrix is formed in the process. Further, '349 teach vortexing or vigorous shaking for forming the nano or microparticles, which are "non-crystalline or amorphous". Thus, the process reads on the instant shear force and accordingly, results in a free flowing substance. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to mix a drug that is poorly soluble with a stabilizer such as surfactant that increases the wettability of the drug and prepare particles by the process of '349 because the process taught by '349 results in amorphous and non-crystalline particles of lower than 150 nm, which is also the particle size range claimed and '349 teach that such amorphous particles (called super cooled particles) increase the wettability of the otherwise insoluble substances. Therefore, one of an ordinary skill in the art would expect an improved delivery with increased bioavailability (col. 14). '349 do not teach the claimed additives, excipients, carriers etc. However, incorporating the above in drug delivery compositions is routine and accordingly would have been obvious for a skilled artisan to achieve the art recognized effect.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615
June 30, 2003